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10/520,521	11/15/2005	Dominique Bernard	1032487-000010	9358

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EXAMINER	
KAM, CHIH MIN	

ART UNIT	PAPER NUMBER
1656	

NOTIFICATION DATE	DELIVERY MODE
05/21/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ADIPFDD@bipc.com

Office Action Summary	Application No.	Applicant(s)	
	10/520,521	BERNARD ET AL.	
	Examiner	Art Unit	
	CHIH-MIN KAM	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 February 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11,28-35,46-51 and 53* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,4,6-11,28,49-51 and 53* is/are rejected.

7)☒ Claim(s) *2,5,29-35 and 46-48* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *07 January 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)

2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/3/07*.

4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.

5) ☐ Notice of Informal Patent Application

6) ☒ Other: *sequence match*.

DETAILED ACTION

Status of the Claims

1. Claims 1-11, 28-35, 46-51 and 53 are pending.

Applicants' amendments filed December 3, 2007 and February 20, 2008 are acknowledged. Applicant's response has been fully considered. Claims 1, 2, 5-8, 10, 11, 28, 35 and 48 have been amended, claims 36 and 52 have been cancelled, and new claim 53 has been added. Therefore, claims 1-11, 28-35, 46-51 and 53 are examined.

Withdrawn Informalities

2. The previous objection to the specification is withdrawn in view of applicants' amendment to the specification, and applicants' response at pages 9-10 in the amendment filed December 3, 2007.

Withdrawn Claim Objections

3. The previous objection to claims 1-11, 28-35, 46 and 47 is withdrawn in view of applicants' amendment to the claims, and applicants' response at page 10 in the amendment filed December 3, 2007.

Withdrawn Claim Rejections - 35 USC § 112

4. The previous rejection of claims 2, 5 and 48 under 35 U.S.C. 112, first paragraph, written description, is withdrawn in view of applicants' amendment to the claims in the amendment filed December 25, 2007.

5. The previous rejection of claims 5-11, 35 and 49-51 under 35 U.S.C. 112, second paragraph, regarding the term "a hydrophilic or hydrophobic targeting agent" or "derived from",

or the outcome of the treatment, is withdrawn in view of applicants' amendment to the claims, and applicants' response at pages 13-14 in the amendment filed December 3, 2007.

Withdrawn Claim Rejections - 35 USC § 103(a)

6. The previous rejection of claim 2 under 35 U.S.C. 103(a) as being unpatentable over Isogai *et al.* (U.S. Patent 6,979,557), is withdrawn in view of applicants' amendment to the claims, and applicants' response at pages 14-15 of the amendment filed December 3, 2007.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 7-11, 50 and 51 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The specification is not enabling for a method for combating skin conditions associated with a dysfunction of cell proliferation and/or differentiation associated with corneodesmosin degradation or treating a dermatological infection associated with corneodesmosin degradation, comprising administering the composition comprising an effective amount of at least one polypeptide of SEQ ID NO:4, 5 or 6, homologs thereof, or a mixture derived from the proteolysis of the polypeptide.

Claims 7-11, 50 and 51 are directed to a method for combating skin conditions associated with a dysfunction of cell proliferation and/or differentiation associated with corneodesmosin

degradation or treating a dermatological infection associated with corneodesmosin degradation, comprising administering the composition comprising an effective amount of at least one polypeptide of SEQ ID NO:4, 5 or 6, homologs thereof, or a mixture derived from the proteolysis of the polypeptide. The specification, however, only discloses cursory conclusions (pages 15-16) without data supporting the findings, which state that the invention relates to a composition comprising SASPase polypeptides and the use of the composition for compensating for an imbalance in epidermal differentiation/proliferation such as regulating the phenomena of moisturization, inflammation, melanogenesis and/or desquamation, or treating dermatological disorders related to keratinization conditions. There are no indicia that the present application enables the full scope in view of the claimed method using the composition as discussed in the stated rejection. The present application does not provide teaching/guidance as to enable the full scope of the claims. The factors considered in determining whether undue experimentation is required, are summarized in In re Wands (858 F2d at 731,737, 8 USPQ2d at 1400,1404 (Fed. Cir.1988)). The factors most relevant to this rejection are the breadth of the claims, the absence or presence of working examples, the state of the prior art and relative skill of those in the art, the predictability or unpredictability of the art, the nature of the art, the amount of direction or guidance presented, and the amount of experimentation necessary.

(1). The breadth of the claims:

The breadth of the claims is broad and encompasses unspecified variants regarding the homologs or the proteolytic peptide mixtures of SASPase polypeptides in the composition, and the effects of the composition in the treating the skin conditions, which are not adequately described or demonstrated in the specification.

(2). The absence or presence of working examples:

There are no working examples indicating the use/effects of the composition in combating skin conditions associated with a dysfunction of cell proliferation and/or differentiation associated with corneodesmosin degradation, or in treating a dermatological infection associated with corneodesmosin degradation. Example XI merely shows the use of SEQ ID NO:6 in decreasing the percentage of residual corneodesmosin.

(3). The state of the prior art and relative skill of those in the art:

While the related art (e.g., Isogai *et al.*, U.S. Patent 6,979,557) teaches the full length nucleotide sequence of the cDNA of NT2NE20005500 and amino acid sequence encoded by the nucleotide sequence has been determined (see Table 1, SEQ ID NO:2323), and the amino acid sequence of SEQ ID NO:2323 containing 343 amino acids has 100% sequence identity to the sequence of SEQ ID NO:6 (138 amino acids) or 99.7% sequence identity to the sequence of SEQ ID NO:5 (343 amino acids), the general knowledge and level of the skill in the art do not supplement the omitted description (i.e., the use/effects of the composition in treating skin conditions associated with a dysfunction of cell proliferation and/or differentiation associated with corneodesmosin degradation), the specification needs to provide specific guidance on identities of the homologs or the proteolytic peptide mixtures of SASPase polypeptides in the composition and their effects in the treatment of various akin diseases to be considered enabling for the variant.

(4). Predictability or unpredictability of the art:

The specification has shown the use of SEQ ID NO:6 in decreasing the percentage of residual corneodesmosin. However, the specification has not demonstrated the use/effect of the

composition comprising SASPase polypeptides or homologs or the proteolytic peptide mixtures of SASPase polypeptides in the treatment of skin conditions related dysfunction of cell proliferation and/or differentiation associated with corneodesmosin degradation. The invention is highly unpredictable regarding the effect of the composition in the treatment of these skin conditions.

(5). The amount of direction or guidance presented and the quantity of experimentation necessary:

The claims are directed to a method for combating skin conditions associated with a dysfunction of cell proliferation and/or differentiation associated with corneodesmosin degradation, or treating a dermatological infection associated with corneodesmosin degradation, comprising administering the composition comprising an effective amount of at least one polypeptide of SEQ ID NO:4, 5 or 6, homologs thereof, or a mixture derived from the proteolysis of the polypeptide. The specification indicates a polypeptide having the sequence of SEQ ID NO:5 and isolated from human keratinocytes belongs to aspartic acid protease family (SASPase), where the polypeptide is autocatalytic and generates specific active form of SEQ ID NO:6 or active sequences of SEQ ID NO:16, 25 and 27 (pages 2-4; Examples I-IV) and the use of SEQ ID NO:6 in decreasing the percentage of residual corneodesmosin (Example XI). However, the specification has not demonstrated the use/effect of the composition comprising SASPase polypeptides or homologs or the proteolytic peptide mixtures of SASPase polypeptides in the treatment of skin conditions related dysfunction of cell proliferation and/or differentiation or a dermatological infection associated with corneodesmosin degradation. There are no working examples indicating the use/effect of the composition comprising SASPase polypeptides

or homologs or the proteolytic peptide mixtures of SASPase polypeptides in the treatment of skin conditions related dysfunction of cell proliferation and/or differentiation. Furthermore, there is no data indicating the correlation between the *in vitro* effect and *in vivo* treatment. Since the specification fails to provide sufficient teachings on the use and effect of the composition in the treatment of these skin conditions, it is necessary to carry out undue experimentation to identify a composition comprising the active SASPase polypeptide and to assess its effect in the treatment of these skin conditions.

(6). Nature of the Invention

The scope of the claims encompasses a method of combating skin conditions associated with a dysfunction of cell proliferation and/or differentiation or treating a dermatological infection using a SASPase polypeptide, but the specification does not demonstrate the use and the effect of the composition comprising a SASPase polypeptide in the claimed method. Thus, the disclosure is not enabling for the reasons discussed above.

In summary, the scope of the claim is broad, the working example does not demonstrate the claimed methods associated with variants, the effect of the composition for in vivo treatment is unpredictable, and the teachings in the specification are limited, therefore, it is necessary to carry out undue experimentation to identify an active SASPase polypeptide and to assess its effect in the claimed method.

Response to Arguments

Applicants indicate claims 7 and 10 have been amended to specify that the skin conditions associated with a dysfunction of cell proliferation and/or differentiation (claim 7) and a dermatological infection (claim 10) are associated with corneodesmosin degradation. New

claim 53 is drawn to a method for degrading corneodesmosin in corneocytes comprising applying to corneocytes an effective corneodesmosin degrading amount of at least one polypeptide, the peptide sequence of which comprises at least one sequence selected from the group consisting of SEQ ID NO: 4, SEQ ID NO: 5 and SEQ ID NO: 6. Thus, all of claims 7-11, 50, 51 and 53 require corneodesmosin degradation or treatment of a condition associated with corneodesmosin degradation; and corneodesmosin degradation is clearly shown in EXAMPLE XI of the specification. Furthermore, corneodesmosin is a marker of desquamation (See page 8, lines 28-30 of specification), and EXAMPLE XI clearly proves the ability to hydrolyze corneodesmosin and thus to be effective for treating related disorders. The specification discloses that the peptides can be particularly useful in order to compensate for an imbalance in epidermal differentiation/proliferation, and thus are useful in various dermatological disorders (See pages 15-18). Moreover, applicants are submitting a number of literature publications, abstracts and a WO publication (see Form PTO-1449) to prove that the link between corneodesmosin degradation and the conditions specified in Claims 7, 9, 10 and 11. Regarding the term "homolog", a homolog of a polypeptide or of a peptide sequence is intended to mean any polypeptide or peptide sequence having at least 85%, especially 90%, particularly 95% sequence homology and the same type of biological activity as the polypeptide or peptide sequence (See page 4, lines 4-12). As for identifying suitable homologs or mixtures derived from the proteolysis of the peptide, no more than routine experimentation would be involved in testing such materials in the procedures of EXAMPLE XI. In view of the foregoing, the skilled person would consider the written description to be sufficient and the claims are

enabled. Accordingly, the rejection under 35 U.S.C. 112, first paragraph should be withdrawn (pages 10-13 of the response).

Applicants' response has been considered. However, the arguments are not fully persuasive because of the following reasons. While the corneodesmosin degradation is shown to be involved in the process of desquamation in the literature, and the specification discloses SASPase peptides can degradate corneodesmosin *in vitro* (See Example XI), the specification has not shown the use/effect of SASPase peptides, homologs thereof or the proteolytic peptide mixtures of SASPase peptides in the treatment of skin conditions related to a dysfunction of cell proliferation and/or differentiation or a dermatological infection associated with corneodesmosin degradation. Furthermore, the specification has not demonstrated the correlation between the *in vitro* effect of SASPase peptides and its *in vivo* treatment of various skin conditions associated with corneodesmosin degradation. Regarding the homologs and proteolytic mixtures of SASPase polypeptides, since the correlation between the structure and function of SASPase peptide variants is not described, one skilled in the art would not know which SASPase peptide variant is functional. Thus, it requires undue experimentation to identify an active SASPase peptide variant and to assess its effect in the treatment of various skin conditions associated with corneodesmosin degradation. Therefore, the rejection under 35 U.S.C. 112, first paragraph is maintained.

8. Claims 1, 3, 4, 6-11, 49-51 and 53 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled

in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 1, 3, 4, 6-11, 49-51 and 53 are directed to a cosmetic or pharmaceutical composition comprising at least one polypeptide of SEQ ID NO:4, 5 or 6 and homologs thereof; a cosmetic or pharmaceutical composition comprising at least one polypeptide mixture obtained from the proteolysis of a polypeptide, the polypeptide sequence being SEQ ID NO:4, 5 or 6 and homologs thereof; and a method for combating skin conditions combating associated with a dysfunction of cell proliferation and/or differentiation associated with corneodesmosin degradation, treating a dermatological infection associated with corneodesmosin degradation, or degrading corneodesmosin in corneocytes, comprising applying the composition comprising the polypeptide to the skin or corneocytes.

In *University of California v. Eli Lilly & Co.*, 43 USPQ2d 1938, the Court of Appeals for the Federal Circuit has held that "A written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials". As indicated in MPEP § 2163, the written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show that Applicant was in possession of the claimed genus. In addition, MPEP § 2163 states that a representative number of

species means that the species which are adequately described are representative of the entire genus. Thus, when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus.

While the specification indicates the present invention is related to a polypeptide having the sequence of SEQ ID NO:5 and isolated from human keratinocytes belongs to aspartic acid protease family (SASPase), where the polypeptide is autocatalytic and generates specific active form of SEQ ID NO:6 or active sequences of SEQ ID NO:16, 25 and 27 (pages 2-4; Examples I-IV) and the use of SEQ ID NO:6 in decreasing the percentage of residual corneodesmosin (Example XI), the specification does not disclose a genus of variants for homologs of SASPase polypeptides or for polypeptide mixture obtained from the proteolysis of the SASPase polypeptides, and the use of these SASPase polypeptide variants in the treatment. Without guidance on structure to function/activity of SASPase polypeptide variants, one skilled in the art would not know which SASPase polypeptide variant is functional. A specific example of active form of SEQ ID NO:6 does not provide a sufficient written description for genus of variants of numerous SASPase polypeptide variants as encompassed by the claims. The lack of description on function/activity of SASPase polypeptide variants including homologs or peptide mixtures of proteolysis, and lack of representative species as encompassed by the claims, applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise terms that a skilled artisan would not recognize applicants were in possession of the claimed invention.

Regarding response to arguments, please see the section in paragraph 7.

Maintained Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. Claims 1 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Isogai *et al.* (U.S. Patent 6,979,557 B2).

Isogai *et al.* teach a cDNA derived from human such as NT2NE20005500 has been isolated, and the full length nucleotide sequence of the cDNA and amino acid sequence encoded by the nucleotide sequence has been determined (see Table 1, SEQ ID NO:2323), and the amino acid sequence of SEQ ID NO:2323 (343 amino acids) has 100% sequence identity to the sequence of SEQ ID NO:6 (138 amino acids), and 99.7% sequence identity to the sequence of SEQ ID NO:5 (see attached sequence match), thus the amino acid sequence of SEQ ID NO:2323 is the homolog of SEQ ID NO:5. The reference also teaches the polypeptide encoded by the full-length cDNA can be prepared as a recombinant polypeptide or a natural polypeptide (column 29, lines 39-58; claim 28), and the polypeptides which may be involved in a disease are useful of developing a diagnostic marker or a medicine for regulation of their expression and activity, or as a target of gene therapy, thus the polypeptides can be formulated in a pharmaceutical composition (column 49, lines 14-28; column 64, line 65- column 65, line 20; claim 1). Although the reference does not specifically indicate the amino acid sequence of SEQ ID NO:2323 being isolated or used as a pharmaceutical composition, it does suggest the polypeptide can be recombinantly produced and used in a pharmaceutical composition. At the time of invention was

made, it would have been obvious to one of ordinary skill in the art that the polypeptide of SEQ ID NO:2323 taught by Isogai *et al.* can be isolated and prepared as a pharmaceutical composition because the cDNA encoding the polypeptide is isolated and the polypeptide can be produced recombinantly and tested, which results in the claimed invention and were, as a whole, prima facie obvious at the time the claimed invention was made. Claim 28 is directed to an isolated peptide having (reads as comprising) a peptide sequence consisting of SEQ ID NO:6, thus the polypeptide of SEQ ID NO:2323 meets the criteria of claim 28.

Response to Arguments

Applicants indicate claims 1, 2 and 28 have been amended to recite "a peptide consisting of", and SEQ ID NO:2323 of Isogai *et al.* comprises SEQ ID NO:6, but is not SEQ ID NO:6. The amended claim language clearly excludes an amino acid sequence such as SEQ ID NO: 2323. Furthermore, this document is completely silent concerning the use of the polypeptides for the preparation of cosmetic/pharmaceutical compositions according to the instant invention, i,e, compositions of such a polypeptide in a physiologically acceptable medium. Moreover, no data in Isogai *et al.* demonstrate the therapeutic uses of such polypeptides, and even less the uses as claimed. In view of the foregoing, the rejection should be withdrawn (pages 14-16 of the response).

Applicants' response has been considered. Regarding claim 2, the argument is persuasive and the rejection is withdrawn. Regarding claims 1 and 28, the arguments are not fully persuasive because of the following reasons. Isogai *et al.* teach the amino acid sequence of SEQ ID NO:2323 (343 amino acids) has 100% sequence identity to the sequence of SEQ ID NO:6 (138 amino acids), thus the amino acid sequence of SEQ ID NO:2323 comprises SEQ ID NO:6,

which meets the criteria of claim 28 because claim 28 reads an isolated peptide having (means comprising) a peptide sequence consisting of SEQ ID NO:6. Furthermore, the amino acid sequence of SEQ ID NO:2323, which has 99.7% sequence identity to the sequence of SEQ ID NO:5, is the homolog of SEQ ID NO:5, and Isogai *et al.* also teach the polypeptides which may be involved in a disease are useful of developing a diagnostic marker or a medicine for regulation of their expression and activity, or as a target of gene therapy, thus the polypeptides can be formulated in a pharmaceutical composition (column 49, lines 14-28; column 64, line 65-column 65, line 20; claim 1). In view of the teachings of Isogai *et al.*, the rejection of claims 1 and 28 is maintained.

Conclusion

10. Claims 1, 3, 4, 6-11, 28, 49-51 and 53 are rejected; and claims 2, 5, 29-35 and 46-48 are objected to.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Bragdon can be reached at 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Chih-Min Kam/
Primary Examiner, Art Unit 1656

CMK
May 16, 2008